

Structured Product Labeling (SPL) OTC Sub-team Teleconference

July 13, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

- + Cheryl Blik, Teva Pharmaceuticals USA
- + David Brown, Colgate-Palmolive
- + Pete Carlson, Ecolab
- + Mary Beth Fritz, Prestige Brands Holdings, Inc.
- + Juris Lazdins, Novartis Consumer Health, Inc.
- + Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
- + Kathryn Moreng, Bayer Consumer Healthcare
- + Devon Morgan, Perrigo Company (sub-team co-leader)
- + Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
- + Jeff Poisson, i4i
- + Alison Rago, Intagras
- + Janet Riffitts, McNeil Consumer Healthcare
- + Gary Saner, Reed Technology and Information Services, Inc.
- + Howard Shatz, Data Conversion Laboratory, Inc.
- + Karen Stith, Image Solutions
- + Carl Strotz, Wyeth Consumer Healthcare
- + Craig Trautman, Intagras
- + Karen Vescovi, Church & Dwight Co., Inc.
- + Ann Vu, FDA
- + Barbara Wolfe, Wyeth Consumer Healthcare
- + Reese Zade, Dr. Reddy's Laboratories, Inc.
- + Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: July 27, 2009 (unless cancelled)

III. Discussion Topics

A. NLM Pillbox Initiative

Key questions and considerations

- Confirm companies will submit samples of products to be photographed to NLM (or will they come from the companies).
- What is the source of the photos, *i.e.*, who provides the images?
- Who will be responsible for posting the images, and how would updates and changes be processed?
- If NLM produces the photos, what chain of custody and processes are/need to be in place to ensure accuracy of medication photographed (*i.e.*, how will NLM ensure that the accuracy of the sample is what is captured?)?

- What internal corporate resources, if any, will be needed to participate in the initiative?
- Will the Pillbox initiative replace the PDR or will there be two sources of information?
- As some companies also post images on their own websites, what is the potential impact, if any, on having the images posted at corporate websites as well as NLM?
- Would it be possible to link the image with SPL submissions?
- Will both sides of the medicine be photographed even imprints are only on one side?
- What happens if the shape of the tablet is copyrighted or trademarked?

Marcia Howard (CHPA) will contact David Hale (NLM) to arrange for him and any necessary technical staff to participate on a teleconference with sub-team members. [Initiated July 14, 2009] Sub-team members should invite internal colleagues as necessary to participate on the call when finalized.

B. Posting OTC information to DailyMed/FDA Facts page

There was discussion based on a document outlining possible pros and cons of having OTC monograph products posted to NLM DailyMed. Additional comments are provided on revised document (see below). Sub-team members were asked to review revised document and provide any feedback.

FDA has asked for input about whether or not drug listing information for monograph products should be made publicly available. If the sub-team can reach an agreement on a recommendation (*e.g.*, proceed as with ANDA/NDA OTC product listings, proceed with caveats as outlined, or do not post with rationale), comments will be submitted to the agency. If no consensus is reached, there will be no further action taken. However, companies are encouraged to provide their own feedback to FDA regardless of the decision of the sub-team. Although no timeframe was given, comments should be sent as soon as possible.

IV. FDA Data Council Information (*not all-inclusive*)

- A. The FDA Data Standards Council's Stability Data Standard web page was updated Thursday, June 4, 2009, to provide the following updated documents:
1. Stability data schema
 2. Implementation Guide
 3. Input Tool Requirements

The three aforementioned documents are accessible via this web page:

<http://www.fda.gov/ForIndustry/DataStandards/StabilityDataStandard/default.htm>

- B. The FDA Data Standards Council's Regulated Product Submission (RPS) web page was updated on Monday, June 15, 2009, to include updated information about Release One and Release Two as well as a link to the HL7 RPS website.

<http://www.fda.gov/ForIndustry/DataStandards/RegulatedProductSubmission/default.htm>

- C. The FDA Data Standards Council's SPL web page was updated today, June 16, 2009, to provide an update to the UNII's list.

1. SPL web page

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm> -

Updated to include links to:

2. UNII list with synonyms

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM166892.zip>

3. XML terminology files with only preferred terms for substances and UNII's

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM166894.zip>

- D. The FDA Data Standards Council's website was updated Monday, June 22, 2009, to include updated terminology lists:

1. UNII's (now over 10,000 UNII's publically available) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>

2. Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM168393.zip>

3. Postal Code Validation List (addition of "PAN" for Panama) -

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM168394.zip>

- E. The FDA Data Standards Council's website was updated Wednesday, June 24, 2009, to include a new package type "PATCH" and more SPL R4 training sessions (see VI.A. below for information on the R4 training sessions)

1. New package term: "Patch" -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm163380.htm>

2. Updated package type terminology XML file -

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM169000.zip>

F. Instructions for removing Thumbs.db files

Thanks to Ted Hanebach for providing the instructions for removing the Thumbs.db file. This is one of the most common errors in SPL R4 document submitted for the purpose of registering a drug establishment or listing a drug. "To stop your computer from generating and regenerating future Thumbs.db files, do the following:

If you're on the desktop...

1. Click Start
2. Double-click Control Panel
3. Double-click Folder Options

Or, if you have My Computer open and are browsing any folder in your system...

1. Click Tools (next to File, Edit, View at the top of the screen)
2. Click Folder Options

After performing either of those two operations, the "Folder Options" window will open up.

1. Click on the View tab
2. Check off the circle next to Do not cache thumbnails
3. Click the Ok button

Once you click the Ok button, your computer will cease to generate Thumbs.db files. If you delete any of the existing Thumbs.db files, they will not return. Be forewarned though, if you browse a folder that contains a large quantity of image files (or extremely large image files), it will take a long time for that folder to load even if you have previously browsed it because the thumbnail images will not have been cached in Thumbs.db."

V. Open Discussion by Sub-team Members

- One sub-team member has experienced problems with the official DailyMed pdf not mapping correctly for OTCs. Craig Trautman (Intagras) recommended contacting Lonnie Smith (FDA) for a technical description of the pdf to troubleshoot.
- Highlights from FDA Q&A session from July 13, 2009
 - Companies can ignore the validation error message from Pragmatic Validator Lite™ if you are **requesting** a labeler code. Note new address to obtain validator due to recent FDA website update:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>.
 - FDA may have to discuss how to handle UNII requests for proprietary ingredients for which manufacturers do not have information about formulations.

- If a company has filed an application and is submitting the content of labeling for review but doesn't want the info posted to DailyMed, it may not be necessary to submit a SPL product listing file.

VI. Upcoming SPL Educational Forums

- A. FDA SPL R4 Training Sessions, including sessions on Repacked drug products, Combination products, Common errors in SPL R4 submissions, homeopathic drug products. See website for a complete listing.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

If you sign-up for a training session and do not receive confirmation at least 24 hours before the session begins, it is recommended that you contact Lonnie to confirm your registration.

Slides from the various training sessions that can be shared publicly are available at the SPL wiki page.

- B. FDA weekly SPL R4 Q&A/Training session
June 8, 2009 – December 28, 2009
Mondays (except Federal holidays; no session held on June 22nd)
11:30 a.m. – 12:00 p.m. EST

Audio conference details:

Telephone number: 1-866-775-9435
Participant pass code: 2219058

- C. DIA SPL Workshop (August 11-12, 2009; The Westin Philadelphia, Philadelphia, PA)

<http://www.diahome.org/DIAHOME/Education/FindEducationalOffering.aspx?productID=20798&eventType=Meeting>
Early bird registration and discounted hotel rates expire July 21, 2009

REVISED OTC Product Listing to NLM DailyMed Website - Possible Pros and Cons

NOT FOR CIRCULATION

Revisions shown in blue

Key Issues:

- Should OTC product listing information submitted to FDA be made publicly available?
- If so, where should this information be listed to best ensure consumer access (e.g., NLM DailyMed, FDA website, other???)

Pros (listed randomly):

- Companies would be able to direct third party clients to website for information vs. having to respond to each individual request for information. **The website could also be beneficial when international organizations and authorities request information from an “FDA recognized” website.**
- Companies maintain control of data that is posted through their electronic submissions.
- FDA currently posting NDA & ANDA drug product listing so posting all OTC information would provide consistency.
- OTC products will be seen as “real” medicines that are treated like other human drug products, **i.e., gives validity to premise that OTCs are “real” drugs.**
- **Healthcare professionals should/could use website to determine drug interactions with other products.**
- Having the data publicly available will enhance search capabilities **for the agency, trade associations, and industry** for product ingredients especially when safety concerns arise.
- If the NLM Pillbox initiative is extended to OTC products, the posting information may be needed to coordinate the activity.
- **There is the possibility for enhances transparency – consumers would have access to the most current information and may encourage better compliance.**

Cons (listed randomly):

- Is there any concern that counterfeiters will use posted label information for illegal activities? (During the call it was noted that counterfeiters can purchase the product to obtain the actual label so probably not much of a concern.)
- Are there any liability concerns regarding the information posted (e.g., representative label is posted which consumer accesses but has adverse event based on product with a slightly different label)?
- Is the NLM DailyMed website the most appropriate place to have the data listed or is another more consumer-friendly or accessible website such as the FDA consumer page a better choice? Should or could the info be listed at two sites?
- Is there any information that companies are concerned may be released to competitors? (During the call it was suggested that there is probably no more concern for monograph products than for ANDA/NDA products.)

Questions (listed randomly):

- How would active and inactive ingredients be listed?
- Is there a rational reason why OTC monograph products should not be listed?
- Who is the target audience – healthcare professionals, consumers, or both? If both, is it possible for a single website to reach both groups? The consumer site would need to be user-friendly.
- What is the potential timing for posting the information?
 - If too little information is made available at the beginning, consumers may be discouraged from visiting the site if too few products are listed.
 - A contrasting opinion was that by having the information publicly available, consumers may be encouraged to seek information resulting in enhanced compliance.